UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BEATRICE M. HEGHMANN and ROBERT A. HEGHMANN, Plaintiffs, v. KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services, NANCY-ANN DEPARLE, Director, White House Office of Health Reform, and CHARLENE FRIZZERA, Administrator, Centers For Medicare and Medicaid Services, Defendants.	09 Civ. 5880 (BSJ)

Government's Motion to Dismiss the Amended Complaint Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6)

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Preliminary Statement

Defendants (the "government") respectfully submit this motion to dismiss the amended complaint ("complaint") in this case for lack of subject matter jurisdiction and for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). Plaintiffs assert an assortment of generalized grievances concerning health-care-related legislation and vaguely sinister speculation about planned governmental actions, but no particular actual or imminent injuries they themselves suffered. They therefore lack standing to sue. They also challenge bills that have not been enacted and regulations that have not been promulgated, claims that cannot meet the jurisdictional requirement of ripeness. Finally, plaintiffs' arguments are unsupported by any law, and they have therefore failed to state a claim. The complaint must therefore be dismissed.

Background

A. Procedural History

Plaintiff Beatrice Heghmann, represented by her husband Robert Heghmann, filed this action on June 25, 2009. With disbarment proceedings in this Court pending against Robert Heghmann, plaintiffs elected to amend the complaint to add Robert Heghmann as a plaintiff and proceed pro se;[1] the amended complaint is dated September 28, 2009.[2]

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[1] As other courts have noted, "'Mr. Heghmann . . . is no stranger to pro se litigation, at least some of which has been meritless. *See* [*Heghmann v. Fermanian*, 2000 WL 1742122, at *4 (D. Me. Nov. 27, 2000)] (awarding sanctions against Heghmann and concluding that his "claims in this action were without merit from the beginning and would have been perceived as such by any objectively reasonable attorney.").'" *Heghmann v. Maguire*, No. 06-cv-003, slip op. at 2 (D.N.H. May 23, 2006) (quoting *Heghmann v. Town of Rye*, No. 04-100-SM, 2004 WL 2526417, at *1 (D.N.H. Nov. 8, 2004)).

[2] The amended complaint has apparently not been filed with the clerk of this Court, as it does not appear on the docket sheet.

B. Plaintiffs' Allegations

Plaintiffs primarily attack the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), which appears as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 ("ARRA"), Pub. L. No. 111-5 (2009). Plaintiffs seek to enjoin the provisions of the HITECH Act that promote the use of electronic health records ("EHRs") and the expenditure of funds ARRA appropriates for this purpose. Plaintiffs contend that the White House Office of Health Reform is "designing a new system for delivering medical care to every person in the United States" which, pursuant to the HITECH Act, allegedly would result in the Office of the National Coordinator for Health Information Technology ("ONC")'s supervising health care information of people who are currently enrolled in private insurance. Compl. ¶¶ 11–16. Plaintiffs contend that the HITECH Act also undermines the Privacy Rule adopted under the Health Insurance Portability and Accountability Act ("HIPAA") by requiring the Secretary of Health and Human Services to amend the Privacy Rule to make it consistent with the HITECH Act's provisions, *id.* ¶ 17, and authorizing the Secretary to issue guidance on the "minimum necessary" standard for disclosure of protected health information and de-identification of information, *id.* ¶¶ 19–21. Plaintiffs further allege that the comparative effectiveness research authorized by ARRA will result in the ONC and the Office of Health Reform's monitoring treatments to ensure that plaintiffs' doctor is providing services that the federal government deems appropriate. *Id.* ¶¶ 22, 27–28. Plaintiffs allege that the HITECH Act empowers the ONC to impose sanctions on health care providers who do not follow the ONC's decisions regarding appropriate treatment because they are not "meaningful users" of EHR technology. *Id.* ¶ 28. Plaintiffs also assert that the HITECH Act's requirements will effectively terminate the accrediting function of

the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO"), because American healthcare providers, like their Canadian counterparts in the 1950s, will no longer be able to meet JCAHO's high standards for safety and patient care. *Id.* ¶¶ 32–33. According to plaintiffs, this federal interference in health care decision making will undermine their personal security, contrary to the Constitution. *Id.* ¶¶ 51–52.

Plaintiffs also allege that Mrs. Heghmann, as a health care professional and as a payer of health insurance premiums, has been adversely affected by the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd ("EMTALA"), because EMTALA requires that hospitals provide care to anyone needing emergency treatment. Compl. ¶¶ 73–78. Plaintiffs assert that EMTALA is thus an unconstitutional taking. *Id.* ¶ 78. Plaintiffs further claim that Medicare underpays health care expenses, and that if a public plan option is enacted as part of health care reform that extends these underpayments to other hospitals, it would also be an unconstitutional taking. *Id.* ¶ 67–71. Finally, plaintiffs allege that the White House Office of Health Reform and the Department of Health and Human Services ("HHS") have violated the Privacy Act by sharing information without observing Privacy Act restrictions. Compl. ¶¶ 53–56.

C. Statutory and Regulatory Background

1. The HITECH Act and Electronic Health Records

The HITECH Act was enacted on February 17, 2009. In the HITECH Act, Congress expresses a goal that providers in the United States use EHRs for all patients by 2014. HITECH Act § 13101. To encourage adoption of EHR technology, the HITECH Act has three major components. Section 13101 of the HITECH Act adds a new Title XXX to the Public Health Service Act ("PHS Act"), 42 U.S.C. § 201 et seq. It directs the National Coordinator for Health Information Technology and two new advisory committees to assist

in different capacities in the development of federal standards for EHRs. 42 U.S.C. §§ 300jj-11 to 300jj-13. Compliance with these standards is mandatory for federal entities, 42 U.S.C. §§ 300jj-15 & 17901, but expressly voluntary for private entities, *id.* §§ 300jj-16, 300jj-17(d). The HITECH Act also provides financial incentives for Medicare- and Medicaid-participating providers to adopt electronic health records, but does not mandate EHR adoption by such providers. HITECH Act §§ 4101–4102, 4201 (amending 42 U.S.C. §§ 1395w-4, 1395w-23, 1395ww, 1396b). Finally, as discussed below, the HITECH Act amends HIPAA.

The HITECH Act formally establishes the Office of the National Coordinator for Health Information Technology within the Department of Health and Human Services. The HITECH Act directs the National Coordinator to seek to develop a nationwide health information technology infrastructure to enable the electronic use and exchange of health information. 42 U.S.C. § 300jj-11(b), (c). Among other things, the National Coordinator is directed to ensure that patients' health information is secure and protected in accordance with applicable law. *Id.* The Secretary of HHS also must appoint a Chief Privacy Officer to advise the National Coordinator "on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information." *Id.* § 300jj-11(e).

The HITECH Act also establishes two new federal advisory committees, the HIT (i.e., health information technology) Policy Committee and the HIT Standards Committee. *Id.* § 300jj-12 & 300jj-13. The Act specifically requires the HIT Policy Committee to consider and make recommendations regarding technologies to protect the privacy of

health information and promote the security of EHRs; that allow for an accounting of disclosures; that allow for individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals during transmission; and that address the needs of children and other vulnerable populations. *Id.* § 300jj-12(b)(2)(B).

2. HIPAA

a. HIPAA and the Privacy and Security Rules

HIPAA, enacted in 1996, contains a subtitle called "Administrative Simplification." Pub. L. No. 104-191 §§ 261–264. The purpose of those provisions is to "improve [Medicare, Medicaid], and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." *Id.* § 261 (reproduced as 42 U.S.C.A. § 1320d note). Accordingly, Congress directed HHS, among other things, to adopt uniform standards to enable health information to be exchanged electronically. Pub. L. No. 104-191 § 262; 42 U.S.C. § 1320d-2.

At the same time that Congress sought to promote efficiency through the use of electronic information technology in the health care industry, it recognized that the new regulatory scheme it had established for the transmission of medical information posed risks to the privacy of confidential patient information by eroding practical barriers that historically had acted as safeguards against improper access to that information. H.R. Rep. No. 496, 104th Cong., 2d Sess. 1, 99-100, reprinted in 1996 U.S.C.C.A.N. 1865, 1900. Thus, Congress directed HHS to submit "detailed recommendations on standards with respect to the privacy of individually identifiable health information" within one year of the statute's enactment. Pub. L. No. 104-191 § 264(a). Congress specified that those standards should

address "at least" three areas: (1) "[t]he rights that an individual who is a subject of individually identifiable health information should have," (2) "[t]he procedures that should be established for the exercise of such rights," and (3) "[t]he uses and disclosures of such information that should be authorized or required." *Id.* § 264(b).

Accordingly, HHS has published a final rule entitled "Standards for Privacy of Individually Identifiable Health Information" (the "Privacy Rule"). 45 C.F.R. Part 160, Part 164 Subparts A and E. Under the HIPAA Privacy Rule, covered entities[3] may only use or disclose protected health information as required or permitted by the Rule. Subject to certain exceptions, protected health information is "individually identifiable health information" that is held by or on behalf of a covered entity. 45 C.F.R. § 160.103. Individual identifiers are items such as a patient's name, address, and social security number (as well as certain other information identified in the Rule). 45 C.F.R. § 164.514(b)(2). Generally, covered entities must make an individual's protected health information available to the individual who is the subject of the information (the patient or health plan beneficiary) or to their representative, and to the HHS Office for Civil Rights for HIPAA enforcement purposes. 45 C.F.R. §§ 164.502(a)(2)(ii), 164.524. The Privacy Rule also imposes numerous administrative requirements on covered entities, such as providing a notice of privacy practices to individuals and training staff. 45 C.F.R. §§ 164.520, 164.530.

The HIPAA Privacy Rule recognizes the need for certain disclosures in health care delivery and for various public purposes. For example, HIPAA permits disclosures to public health authorities for public health purposes. 45 C.F.R. § 164.512(b). Covered entities are

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[3] "Covered entities" are (1) health care providers that electronically engage in transactions for which HHS has adopted standards, (2) health plans, and (3) health care clearinghouses. 45 C.F.R. §§ 164.103 and 164.500. Health care providers that do not electronically bill health plans or otherwise engage in other electronic transactions for which standards have been adopted are not subject to the Privacy Rule.

permitted to disclose protected health information with the individual's written authorization, or without authorization for a number of specific purposes including treatment, payment, health care operations, public health, and research with certain protections, and to law enforcement agencies and as part of administrative and judicial proceedings if procedural requirements are met. 45 C.F.R. §§ 164.506, 164.512.

The Privacy Rule states that, subject to certain exceptions, "[w]hen using or disclosing protected health information, or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request." 45 C.F.R. § 164.502(b)(1). Each covered entity must determine what it believes constitutes the minimum amount of information necessary based upon the requirements related to disclosures at 45 C.F.R. § 164.514(d)(3), which also permits relying on the "minimum necessary" determination of the recipient in certain situations. However, HHS may, in an investigation or compliance review, find that the covered entity is subject to penalties because it disclosed more than the minimum amount of information necessary or otherwise violated the regulations.

The Administrative Simplification provisions of HIPAA also required HHS to establish national standards for the security of electronic health care information. 42 U.S.C. § 1320d-2(d). The final rule adopting HIPAA standards for security (the "Security Rule") specified a series of administrative, technical, and physical security procedures for covered entities to use and other requirements to assure the confidentiality and integrity of electronic protected health information. 45 C.F.R. §§ 164.302–.318.

b. HITECH Act Updates to HIPAA and Associated Rules

The HITECH Act includes a number of changes in the HIPAA Privacy and Security Rules. HITECH Act §§ 13400–13424. Section 13400 mostly adopts current HIPAA definitions, including that of a health care provider set forth at 45 C.F.R. § 160.103. Sections 13401 and 13404 apply most of the current HIPAA Security Rule and many of the current HIPAA Privacy Rule provisions to business associates of covered entities. Section 13402 requires covered entities and their business associates to provide timely notification in case of a breach of unsecured protected health information. Section 13405(b) requires HHS to issue guidance on compliance with the HIPAA "minimum necessary" requirement; such guidance must be issued by August 17, 2010. Section 13424(c) requires HHS, no later than February 17, 2010, to issue guidance after consultation with stakeholders on "how best to implement the requirements for the de-identification of protected health information under section 164.514(b) of title 45, Code of Federal Regulations."

These changes do not affect other federal or state privacy laws. In fact, section 13421(a) specifically incorporates the HIPAA preemption provision, which states that HIPAA privacy provisions do not preempt contrary state law that is more protective of privacy. 42 U.S.C. § 1320d-7; *see* 45 C.F.R. §§ 160.201–.205. As discussed in the December 28, 2000, preamble to the final HIPAA Privacy Rule, HIPAA also does not impinge the application of other federal privacy rules that are more protective of privacy. HITECH Act section 13421(b) provides that existing HIPAA provisions remain in effect "to the extent they are consistent with" subtitle D of the HITECH Act. The new PHS Act Title XXX, enacted as Subtitle A of the HITECH Act, also provides that it "may not be construed as having any effect on the authorities vested in the Secretary under HIPAA." 42 U.S.C. § 300jj-19(a)(1)(A). Indeed, "[t]he purposes of [the statute] include ensuring that the health

information technology standards and implementation specifications . . . take into account the requirements of HIPAA privacy and security law." *Id.* § 300jj-19(a)(1)(B).

3. EMTALA

EMTALA, 42 U.S.C. § 1395dd(a), requires hospitals with emergency departments to provide medical screening to determine if an emergency medical condition exists for any individual who comes to the emergency department requesting examination or treatment. If the hospital determines that the individual has an emergency medical condition, then the hospital must either stabilize the medical condition or transfer the individual to another facility. *Id.* § 1395dd(b). EMTALA provides that Medicare-participating hospitals and physicians who fail to comply are subject to civil money penalties. *Id.* § 1395dd(d)(1). EMTALA also creates a private right of action for individuals who suffer personal harm as a result of EMTALA violations. *Id.* § 1395dd(d)(2).

ARGUMENT

Plaintiffs' allegations consist of nothing more than general opposition to health care reform, overlain with a thin veneer of constitutional argument. As such, this is precisely the type of case the doctrine of standing is meant to preclude: rather than presenting a genuine "case or controversy" regarding their own personal interests, plaintiffs ask this Court to determine the wisdom and advisability of the actions of a co-equal branch of government. But without a particularized injury to them or government action ripe for review, plaintiffs cannot invoke the Court's jurisdiction. Moreover, their constitutional theories contradict the precedent of the Supreme Court and Second Circuit, and for that reason they have failed to state a claim upon which relief can be granted. For all those reasons, their claims must be dismissed.

A. Plaintiffs Lack Standing

Plaintiffs lack standing to bring any of their claims, and the Court thus lacks jurisdiction.

> [T]he irreducible constitutional minimum of standing contains three elements. First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992) (citations, footnotes, alterations, and internal quotation marks omitted); *accord Port Washington Teachers' Ass'n v. Board of Educ.*, 478 F.3d 494, 498–502 (2d Cir. 2007); *Hamm v. United States*, 483 F.3d 135, 137 (2d Cir. 2007); *London v. Polishook*, 189 F.3d 196, 199 (2d Cir. 1999).

Plaintiffs fail to allege any "concrete and particularized," "actual or imminent" injury that affects them in a "personal and individual way," *Lujan*, 504 U.S. at 560 & n.1, and for that reason alone lack standing to sue.

"[A] plaintiff raising only a generally available grievance about government—claiming only harm to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him than it does the public at large—does not state an Article III case or controversy." *Id.* at 573–74. Nor can a citizen save his suit from that rule by asserting that he is a "taxpayer": "It has long been established . . . that the payment of taxes is generally not enough to establish standing to challenge an action taken by the Federal Government." *Hein v. Freedom from Religion Foundation*, 551 U.S. 587, 593 (2007) (plurality); *accord DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342–48 (2006). The courts will not hear a

plaintiff who asserts "'only the right, possessed by every citizen, to require that the Government be administered according to law and that the public moneys be not wasted. Obviously this general right does not entitle a private citizen to institute in the federal courts a suit . . . .'" *Lujan*, 504 U.S. at 574 (quoting *Fairchild v. Hughes*, 258 U.S. 126, 129–30 (1922) (Brandeis, J.)). Thus, the courts have consistently rejected taxpayer suits. *Id.* (citing as impermissible "taxpayer suits" *Massachusetts v. Mellon*, 262 U.S. 447 (1923), *Doremus v. Board of Ed. of Hawthorne*, 342 U.S. 429 (1952), *United States v. Richardson*, 418 U.S. 166 (1974), and *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208 (1974)).[4] For a court to entertain such a "generalized and attenuated" and "minute and indeterminable" interest, *Hein*, 551 U.S. at 599–600 (internal quotation marks omitted), would be "not to decide a judicial controversy, but to assume a position of authority over the governmental acts of another and co-equal department, an authority which plainly [the courts] do not possess," *Mellon*, 262 U.S. at 488–89, *quoted in Hein*, 551 U.S. at 600, and *Lujan*, 504 U.S. at 574.

Plaintiffs expressly concede in their complaint that their injury for standing purposes is based on their status as taxpayers, and their interest in this suit is to "prevent the expenditure of significant amounts of federal taxpayer dollars to fund an unconstitutional purpose." Compl. ¶ 66. That is insufficient under the many cases cited above barring taxpayer standing. Plaintiffs assert no other injury that can support standing. The central claim of the complaint—that the statutes' encouragement of electronic health records threatens plaintiffs' privacy—is, even if assumed to be valid, no more injurious to plaintiffs than to any other citizen.

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[4] The Supreme Court has recognized only one narrow exception to the rule against taxpayer standing for certain claims brought under the establishment clause of the First Amendment, *Hein*, 551 U.S. at 593, not implicated here.

Indeed, plaintiffs' complaint establishes no basis for the conclusion that they will sustain any injury at all. As detailed above, the HITECH Act does not make electronic health records mandatory for private health care providers. PHS Act § 3006 (as amended by the HITECH Act § 13101, codified at 42 U.S.C. § 300jj-16). To the contrary, even if the government were to make electronic health record technology available to the public,[5] the statute expressly says that it does not require private entities to adopt or use this EHR technology. 42 U.S.C. § 300jj-17(d). Even Medicare and Medicaid providers, while receiving incentives to adopt EHRs, are not required to do so. HITECH Act §§ 4101–4102, 4201 (amending 42 U.S.C. §§ 1395w-4, 1395w-23, 1395ww, 1396b).[6]

Plaintiffs' complaint does not allege that they use any federally provided health care, or even Medicare or Medicaid. Compl. ¶¶ 2, 4. They therefore assert no injury under the statutes they cite. And even if the statutes could be read as plaintiffs assert, they cannot meet the heightened burden of establishing causation and redressability—two of the three elements of constitutional standing—when third parties are regulated:

> When . . . a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*, much more is

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[5] EHR technology will be made available to the public unless the HHS Secretary determines that the needs of providers are being met through the marketplace. 42 U.S.C. § 300jj-17(a).

[6] Although plaintiffs' complaint alleges that "[e]very health care provider is being required to acquire and implement Health Information Technology designed by the Office of Health Reform and HHS," Compl. ¶ 12, that assertion (unaccompanied by any citation) directly contradicts the statutes plaintiffs complain of, and deserves no weight from this Court. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949–50 (2009) (court need not accept "legal conclusions" or "legal conclusion couched as factual allegation" (internal quotation marks omitted)); *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996) ("bald assertions and conclusions of law will not suffice" to defeat a motion to dismiss); *GVA Market Neutral Master Ltd. v. Veras Capital Partners Offshore Fund, Ltd.*, 580 F. Supp. 2d 321, 326 (S.D.N.Y. 2008) ("mere 'conclusions of law or unwarranted deductions' need not be accepted" on motion to dismiss (quoting *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 771 (2d Cir. 1994))).

> needed. In that circumstance, causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction—and perhaps on the response of others as well. The existence of one or more of the essential elements of standing depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict, and it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury.

Lujan, 504 U.S. at 562 (internal quotation marks and citations omitted). That burden is "substantially more difficult" to carry than in a case where the plaintiff is the subject of regulation, *id.*, and plaintiffs cannot meet it here. In fact, they make no allegation whatsoever regarding actions their health providers have taken or will take, and their claims about the effect of electronic health records are speculative in the extreme. They have therefore utterly failed to plead adequate injury, causation, or redressability.[7]

Plaintiffs allege other third-party harms, none of which comes close to establishing standing. They claim that the establishment of the Federal Coordinating Council for Comparative Effectiveness Research, ARRA § 804, 42 U.S.C. § 299b-8, "lays the groundwork for a permanent government rationing board," and the Council will "prescribe what care, procedures or medications [plaintiffs] will receive in place of the doctors chosen by the Plaintiffs and the Plaintiffs themselves." Compl. ¶ 22. That conclusory assertion is completely unsupported by the statute; the Council's purpose is to "foster optimum coordination of comparative effectiveness and related health services research . . . with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of

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[7] Plaintiffs also cannot establish causation and redressability because their complaint targets federal programs rather than federal actions. "'[S]uits challenging, not specifically identifiable Government violations of law, but the particular programs agencies establish to carry out their legal obligations . . . are, even when premised on allegations of several instances of violations of law, . . . rarely if ever appropriate for federal-court adjudication.'" *Lujan*, 504 U.S. at 568 (quoting *Allen v. Wright*, 468 U.S. 737, 759–60 (1984)).

resources," and it is expressly forbidden "to mandate coverage, reimbursement, or other policies for any public or private payer." 42 U.S.C. § 299b-8(a), (g)(1). In a similar vein, plaintiffs allege that the National Coordinator for Health Information Technology "will monitor treatments to make sure the Plaintiff[s'] doctor is doing what the federal government deems appropriate and cost effective." Compl. ¶ 27. That, again, finds no support in the statute, as the National Coordinator is charged with reviewing health information technology standards to ensure the security of patient information, improve health care quality, reduce costs, and the like, 42 U.S.C. § 300jj-11(b), (c); nothing in the statute gives the National Coordinator anything close to the power plaintiffs assert.

Plaintiffs also claim that health-care reform will lead to the demise of the Joint Commission on the Accreditation of Healthcare Organizations, which in turn will lead to the lowering of the quality of American healthcare. Compl. ¶ 33. That is the very definition of a "conjectural or hypothetical" injury, *Lujan*, 504 U.S. at 560 (internal quotation marks omitted)—not to mention "attenuated," "minute," or "indeterminable," each of which is sufficient to defeat standing, *Hein*, 551 U.S. at 599–600 (internal quotation marks omitted). The argument moreover suffers from the same flaw as plaintiffs' other claims, in that it relies on the hypothesized and uncertain actions of third parties—in this case, at least two layers of third parties—and therefore cannot support redressability or causation. *Lujan*, 504 U.S. at 562.

For all those reasons, plaintiffs lack standing and the complaint should be dismissed.

B. Plaintiffs' Claims Are Not Ripe

Plaintiffs' claims are not ripe for review, and therefore are outside the jurisdiction of this Court. "'The ripeness doctrine is drawn both from Article III limitations on judicial

power and from prudential reasons for refusing to exercise jurisdiction,'" *NYCLU v. Grandeau*, 528 F.3d 122, 130–31 (2d Cir. 2008) (quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003)), and serves to "prevent[] a federal court from entangling itself in abstract disagreements over matters that are premature for review because the injury is merely speculative and may never occur," *Ross v. Bank of Am.*, 524 F.3d 217, 226 (2d Cir. 2008) (internal quotation marks omitted).

There are "two overlapping threshold criteria for the exercise of a federal court's jurisdiction" that fall under the term "ripeness." *Simmonds v. INS*, 326 F.3d 351, 356–57 (2d Cir. 2003). The constitutional ripeness doctrine "is a limitation on the power of the judiciary. It prevents courts from declaring the meaning of the law in a vacuum and from constructing generalized legal rules unless the resolution of an actual dispute requires it." *Id.* Prudential ripeness "means that the case will be better decided later and that the parties will not have constitutional rights undermined by the delay," and exists for courts "to enhance the accuracy of their decisions and to avoid becoming embroiled in adjudications that may later turn out to be unnecessary or may require premature examination of, especially, constitutional issues that time may make easier or less controversial." *Id.*, *quoted in Grandeau*, 528 F.3d at 131. Both the constitutional and prudential ripeness inquiries are determined by "a two-step inquiry, 'requiring [courts] to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" *Grandeau*, 528 F.3d at 131–32 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).[8]

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[8] Standing and ripeness are "closely related, most notably in the shared requirement that the injury be imminent rather than conjectural or hypothetical." *Brooklyn Legal Servs. Corp. v. Legal Services Corp.*, 462 F.3d 219, 225 (2d Cir. 2006). The Court may therefore consider the two doctrines together, as encouraged by the Second

(continued...)

Plaintiffs' claims are unripe under this standard, as the HITECH Act has not yet been fully implemented. Specifically, the Act requires the HIT Standards Committee to recommend EHR standards and criteria to the National Coordinator, who then reviews and determines whether to endorse them and pass them to the Secretary of HHS, who then separately reviews them in consultation with other agencies and decides whether to adopt them—a process that has not been completed, and need not be until December 31, 2009. 42 U.S.C. §§ 300jj-11(c), 300jj-13(b), 300jj-14. Similarly, for purposes of Medicare incentive payments, the HHS Secretary has yet to select the "clinical quality standards" on which an "eligible professional" or "eligible hospital" must report to demonstrate meaningful use of EHR technology. HITECH Act §§ 4101(a) (adding 42 U.S.C. § 1395w-4(o)(2)) and 4102(a) (adding 42 U.S.C. § 1395ww(n)(3)).

Second, the pertinent amendments to the HIPAA Privacy Rule do not take effect until February 2010. HITECH Act § 13423. Regarding the same rule, HHS has not yet published guidance on what constitutes the "minimum necessary" disclosure or use of protected health information (which is not required until August 2010), HITECH Act § 13405(b); nor has it published guidance on de-identification of health information (not due till February 2010), HITECH Act § 13424(c).

More generally, most of plaintiffs' claims center on the assertion not that the statutes in question are inherently or facially unconstitutional, but that they will be implemented and enforced in an unconstitutional manner (secretly controlled by Tom Daschle). E.g., Compl. ¶¶ 16, 19, 21, 22, 27–31, 34, 41, 46, 52, 58, 65. But plaintiffs do not even allege that the executive branch has done anything yet. "[A] regulation is not

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[8] (...continued)
Circuit, *id.* at 226; *Grandeau*, 528 F.3d at 130 n.8, and plaintiffs' unripe claims should also be dismissed for lack of standing.

ordinarily considered the type of agency action 'ripe' for judicial review under the APA until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990). Other of plaintiffs' claims are even more patently unripe, as they revolve around unenacted statutes. Compl. ¶¶ 68–71.

Plaintiffs' claims are thus not fit for judicial resolution, nor do plaintiffs allege that there is any hardship to them in following the normal course of waiting until the executive branch takes action to implement the statutes. The Court therefore lacks jurisdiction.

C. Plaintiffs' Claims Regarding Medicare Reimbursement Are Barred by the Medicare Act

The Supreme Court has held that any claim with respect to Medicare payments arising under the Medicare Act, including a constitutional claim, must first be pursued through the administrative review processes laid out in the Medicare Act. *Shalala v. Illinois Council on Long Term Care* 529 U.S. 1, 5, 13–14 (2000); *Heckler v. Ringer*, 466 U.S. 602, 604–05, 614–16 (1984). Plaintiffs claim that Medicare reimburses providers, such as Mrs. Heghmann's employer, an insufficient amount. She alleges these insufficient payments harm her as a hospital employee and a payer of insurance premiums. Thus, at bottom, her claim is one for increased reimbursement to her employer (which she lacks standing to raise anyway). Because the substance of this claim arises under the Medicare Act, the Court lacks jurisdiction to consider it under the above-cited cases because it was not first presented to the HHS Secretary as required by 42 U.S.C. § 1395oo(f).[9]

[9] In addition, the applicable judicial review provision of the Medicare Act requires that suit be brought either in the district where the plaintiffs reside or the District of Columbia. 42 U.S.C. § 1395oo(f)(1). The Southern District of New York is not a proper venue for this claim because plaintiffs reside in New Hampshire. Compl. ¶ 1.

D. Plaintiffs Have Failed to State a Claim

Finally, even if the Court had jurisdiction, plaintiffs' claims fail on the merits as a matter of law, and must be dismissed under Fed. R. Civ. P. 12(b)(6).

1. Standard of Review

In considering a motion to dismiss for failure to state a claim, a court must "assume all 'well-pleaded factual allegations' to be true, and 'determine whether they plausibly give rise to an entitlement to relief.'" *Selevan v. New York Thruway Authority*, __ F.3d __, No. 07-0037-cv, 2009 WL 3296659, at *2 (2d Cir. Oct. 15, 2009) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009)). Pleadings that are "no more than conclusions[] are not entitled to the assumption of truth," and "'[l]abels and conclusions,'" "'naked assertions' devoid of 'further factual enhancement,'" and "the-defendant-unlawfully-harmed-me accusation[s]" are not sufficient to show that a plaintiff is entitled to relief. *Iqbal*, 129 S. Ct. at 1949–50 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 557 (2007)). Instead, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 1949. Nor must a court accept "legal conclusions" or "'a legal conclusion couched as a factual allegation.'" *Id.* at 1949–50 (quoting *Twombly*, 550 U.S. at 555). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950. But the complaint must be dismissed if "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Id.*[10]

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[10] An attorney representing himself is not entitled to the usual liberal construction of his pleadings accorded pro se litigants. *Padilla v. Payco General Am. Credits, Inc.*, 161 F. Supp. 2d 264, 271 (S.D.N.Y. 2001) (citing cases). The same applies to disbarred lawyers. *Moore v. City of New York*, No. 08-cv-2449, 2009 WL 2244735, at *1 n.1 (E.D.N.Y. 2009);

(continued...)

2. Right to Privacy

At the core of plaintiffs' allegations is the claim that their "right to privacy" will be violated. E.g., Compl. ¶¶ 3–4, 35–66. The Supreme Court has recognized "a constitutionally protected 'zone of privacy'" involving "two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of important decisions." *Whalen v. Roe*, 429 U.S. 589, 598–600 (1977).

But while the Constitution recognizes those interests, they are far from unlimited. In fact, the Second Circuit has held that "the right to maintain the confidentiality of personal information is something less than a fundamental right." *Powell v. Schriver*, 175 F.3d 107, 112 n.2 (2d Cir. 1999), *contra* Compl. ¶ 38; *see Grosso v. Town of Clarkstown*, No. 94 Civ. 7722, 1998 WL 566814, at *6–*7 (S.D.N.Y. Sept. 3, 1998) ("conditional right"; discussing cases). Nor is there a blanket constitutional right to the confidentiality of medical information: "the interest in the privacy of medical information will vary with the condition" at issue, and the Constitution's protection has only been held to extend to issues like HIV status, transsexualism, or other "unusual condition[s] that [are] likely to provoke both an intense desire to preserve one's medical confidentiality, as well as hostility and intolerance from others," and are therefore "excruciatingly private and intimate." 175 F.3d at 111; *accord Doe v. City of New York*, 15 F.3d 264, 267 (2d Cir. 1994).

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[10] (...continued)
Presnick v. Bysiewicz, 297 F. Supp. 2d 431, 433 (D. Conn. 2003). Although plaintiff Mrs. Heghmann is not a lawyer, the Court should note that the amended complaint (in which plaintiffs assert they are proceeding pro se) is materially identical to the original complaint, signed by Mr. Heghmann as a lawyer, and therefore deserves no special deference.

And even when such intensely personal medical facts are at issue, the Constitution does not automatically bar disclosures. *Whalen*, in which the Supreme Court considered privacy rights asserted against the government maintenance of computerized medical records, precludes plaintiffs' claims in this case. In that case, the Court upheld a statutory requirement that prescriptions for certain drugs, including "opium and opium derivatives, cocaine, methadone, amphetamines, and methaqualone, [used to treat, e.g.,] epilepsy, narcolepsy, hyperkinesia, and schizo-affective disorders," must be filed with the government, specifying the patient's name, address, and age. 429 U.S. at 592–93 & n.8. Even that highly intrusive and potentially embarrassing disclosure of private medical information to government authorities did not violate the Constitution, as it was not

> meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facets of health care. Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention. Nevertheless, disclosures of private medical information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient. Requiring such disclosures to representatives of the State having responsibility for the health of the community, does not automatically amount to an impermissible invasion of privacy.

Id. at 602 (footnote omitted). More specifically, the Court described numerous instances in which medical information is required by law to be reported to government authorities, such as "statutory reporting requirements relating to venereal disease, child abuse, injuries caused by deadly weapons, and certifications of fetal death," and noted that it had upheld reporting requirements for abortions. *Id.* at 602 n.29. Even while it concluded that medically needed use of the listed drugs had been discouraged by patients' "knowledge that the information is readily available in a computerized file," the Court held that there was no constitutionally undue imposition on confidentiality or on "the right to decide independently, with the advice of [a] physician, [whether] to acquire and to use needed

medication." *Id.* at 602–03. Thus, the Court held that with adequate administrative protections for confidentiality, "neither the immediate nor the threatened impact of the patient-identification requirements . . . on either the reputation or the independence of patients . . . is sufficient to constitute an invasion of any right or liberty protected by the Fourteenth Amendment." *Id.* at 603–04.

Those principles foreclose plaintiffs' claims. The HITECH Act provides for the development of standards for health information technology and electronic health records, but does not itself mandate or authorize any disclosures of health information except for very limited purposes.[11] To the contrary, the HITECH Act repeatedly seeks to limit disclosures of health information. *E.g.*, 42 U.S.C. § 300jj-12(b)(2)(B)(i), (iv) (charging HIT Policy Committee with recommending technology to protect health information from disclosure); HITECH Act § 13402, codified at 42 U.S.C. § 17932 (notification in case of improper disclosure of health information); HITECH Act § 13405, codified at 42 U.S.C. § 17935 (providing numerous provisions to restrict disclosures of health information); HITECH Act § 13409, amending 42 U.S.C. § 1320d-6 (clarifying criminal penalty for wrongful disclosure); HITECH Act § 13410, amending 42 U.S.C. § 1320d-5 (enhancing civil penalties for privacy violations). While the *Whalen* Court relied on the existence of privacy safeguards for highly sensitive medical information in upholding the disclosure

[11] As part of extending HIPAA Privacy Rule protections to the business associates of a covered entity, the HITECH Act amendments to the HIPAA Privacy Rule require a covered entity's business associates to notify it of breaches of protected health information, to give patients a right of access to their own records, and to make records available to HHS for purposes of enforcing the HIPAA Privacy Rule. HITECH §§ 13401, 13402, and 13404. In addition, for purposes of Medicare incentive payments, the HITECH Act authorizes the HHS Secretary to select "clinical quality standards" that Medicare participating "eligible professionals" and "eligible hospitals" would report on to demonstrate "meaningful EHR use." HITECH Act §§ 4101(a) (adding 42 U.S.C. § 1395w-4(o)(2)) and 4102(a) (adding 42 U.S.C. § 1395ww(n)(3)).

requirement there, 429 U.S. at 601–02, 605–06, the HITECH Act also contains extensive privacy protections—those cited in the previous sentence and in Background Point C above (e.g., 42 U.S.C. § 300jj-11 (ONC must ensure privacy, HHS Secretary must appoint privacy officer); HITECH Act § 13400–13424 (updating HIPAA Privacy Rule)). There is therefore no way in which the HITECH Act could infringe upon the constitutional interests in "avoiding disclosure of personal matters." *Id.* at 599. And to the (entirely speculative) extent that the use of electronic health records by health care providers (which is not required by the statute) will make patients reluctant to seek treatment, that potential infringement on their "autonomy and independence in decision-making," *Powell*, 175 F.3d at 111, is orders of magnitude lower than that caused by the system upheld in *Whalen*, where patients' names, addresses, and ages were recorded in an electronic state-maintained database specifying the highly dangerous drugs they used for their highly intimate medical conditions.[12]

Plaintiffs complain that the HITECH Act's modifications of HIPAA and the HIPAA Privacy Rule—in particular, its requirement that HHS issue guidance regarding "minimum necessary" disclosures and "de-identification" of health information[13]—will

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[12] To the extent plaintiffs assert a property interest in their medical records under the due process clause, Compl. ¶¶ 2, 44—contrary to the decisions of the courts, *see Gotkin v. Miller*, 514 F.2d 125, 128–29 (2d Cir. 1975) (no property interest in access to medical records); *Grosso*, 1998 WL 566814, at *7–*8 (no property interest in medical records preventing disclosure to state authority); *Webb v. Goldstein*, 117 F. Supp. 2d 289, 295 (E.D.N.Y. 2000) (no expectation of privacy under Fourth Amendment in medical records possessed by state)—the logic of *Whalen*, holding that there was no infringement of the zone of privacy protected by the due process clause, similarly precludes plaintiffs' property-interest-based claim.

[13] Because information must "identif[y] the individual" to fall within the scope of "protected health information" under the Privacy Rule, information that has been properly de-identified is not subject to the restrictions on disclosure applicable to "protected health information." 42 U.S.C. § 17935(b)(4); 45 C.F.R. § 164.514(a).

"vitiate" privacy protections. Compl. ¶¶ 18–21. Of course, putting aside the obvious unripeness of a challenge to administrative action that has not yet occurred, Congress is free to amend statutes such as HIPAA and supersede regulations such as the HIPAA Privacy Rule. *E.g.*, *Horn Farms, Inc. v. Veneman*, 319 F. Supp. 2d 902, 921 (N.D. Ind. 2004). Plaintiffs further conjecture that doctors' autonomy will be limited, Compl. ¶¶ 27, or that health-care quality will decline, *id.* ¶ 33, but even were those claims not speculative they do not state a constitutional claim. *E.g.*, *Whalen*, 429 U.S. at 603 n.30 (power to regulate medical profession), 604 & n.33 (rejecting physicians' claim against medical disclosure system); *see Gonzales v. Carhart*, 550 U.S. 124 (2007) (upholding federal ban on medical procedure). Finally, plaintiffs allege that supposed exchanges of information between HHS and the White House Office of Health Reform violate the Privacy Act, 5 U.S.C. § 552a(b), Compl. ¶ 55, but fail to state a claim under that statute as they do not allege that they themselves have a record maintained in a system of records by the government or that such a record has been disclosed. *Bechhoefer v. U.S. Dep't of Justice*, 312 F.3d 563, 563–68 (2d Cir. 2002).

3. Takings and Due Process Property Claims

Plaintiffs also claim that Medicare underpays hospitals; that ARRA "contemplates," and "legislation currently under consideration in the Congress anticipates" an expansion of Medicare; costs to hospitals will therefore increase and insurance premiums will go up; thus plaintiffs have been deprived of their property. Compl. ¶¶ 68–71. That this argument challenges unenacted legislation—and is therefore completely impermissible—is only its most obvious flaw. Similarly, plaintiffs allege that EMTALA, by mandating emergency

care, increases costs to hospitals and therefore plaintiffs' insurance premiums, in violation of either the takings or due process clause of the Fifth Amendment. Compl. ¶¶ 73–78.[14]

"Regulatory takings analysis" usually "requires an intensive ad hoc inquiry into the circumstances of each particular case," *Buffalo Teachers Federation v. Tobe*, 464 F.3d 362, 375 (2d Cir. 2006), but here no more than a cursory examination is required. Government regulations often impose some cost on some person somewhere, but "'[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.'" *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 473 (1987) (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 413 (1922) (Holmes, J.)). Thus a regulatory takings claim faces a "heavy burden." *Buffalo Teachers*, 464 F.3d at 375. Courts must consider three factors: "(1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action." *Id.* (internal quotation marks omitted). All three factors decree that no taking has occurred here: the economic impact is totally speculative and minor even if realized; plaintiffs have no investment-backed expectations in future payments of health insurance premiums (the amount of which can change for any number of reasons); and the EMTALA statute—which provides hospital care to those in need of emergency treatment—"burdens the plaintiffs in order to promote the common good." *Id.* Cost shifting is not a taking; "'[g]iven the propriety of the governmental power to regulate, it cannot be said that the Takings Clause is violated whenever the legislation requires one person to use his or

[14] It is unclear from the complaint which clause plaintiffs invoke, but their claims are equally meritless under either.

her assets for the benefit of another.'" *Id.* (quoting *Connolly v. Pension Ben. Guar. Corp.*, 475 U.S. 211, 223 (1986)).

To the extent plaintiffs raise a claim regarding Medicare as a taking, that has already been rejected by the Second Circuit: Medicare is a voluntary program, and therefore cannot give rise to a takings claim. *Garelick v. Sullivan*, 987 F.2d 913, 916-17 (2d Cir. 1993).

* * *

For all those reasons, plaintiffs have failed to state a claim on which relief can be granted.

Conclusion

The complaint should be dismissed.

Dated: New York, New York
October 30, 2009

Respectfully submitted,

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